REMARKS

Claims 1 – 12 and 25 - 33 are pending in the application. Claims 3, 13 – 24, 32 and 33 have been canceled. Claims 1, 4, 12 and 25 - 30 have been amended. Claim 34 has been added. No new matter has been added by virtue of the amendments, support being found throughout the specification and the claims as originally filed.

Any cancellation of the claims should in no way be construed as acquiescence to any of the Examiner's rejections and was done solely to expedite the prosecution of the application. Applicant reserves the right to pursue the claims as originally filed in this or a separate application(s).

Claim Rejections

35 U.S.C. §112, second paragraph

The Examiner has rejected claims 1 – 12 and 25 – 31 under 35 USC §112, second paragraph, as being indefinite for allegedly failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. Applicants respectfully traverse the rejection.

The Examiner has agreed that the language "'at least one detectable moiety' in claim 5 provides sufficient antecedent basis for the limitation 'the detectable moiety or moieties' in claim 6." (Office Action, p.5). Applicants thank the Examiner for reconsideration and withdrawal of the rejection.

The Examiner argues that claim 12 "remains indefinite over the recitation 'wherein in situ hybridization is used for analysis of Psudomonas .'" (Office Action,

p.5). The Examiner argues that "(a)s claim 1 is drawn to a particular product, it is unclear how the recitation of claim 12 might be further limiting." (Office Action, p.5).

Applicants have amended claim 12 to recite that the PNA probe is used in in situ hybridization for analysis of Pseudomonas. Accordingly, the recited language sufficiently limits the features of the claimed product. Applicants respectfully request that the rejection be withdrawn.

The Examiner argues that "claim 26 – 27 remain indefinite because the claims appear to require particular types of method steps, while the claims are drawn to kits (and) it is not clear how the recitations of the claims limit the products that are claimed." (Office Action, p.5).

Applicants have amended the claims to limit the products that are claimed. Accordingly, Applicants respectfully request that the rejection be withdrawn.

The Examiner argues that "claims 1 – 12 and 25 – 31 are indefinite over the recitation of the language 'said PNA probe being complementary to a target sequence of 23S rRNA or rDNA of all species of the genus Pseudomonas, except for Pseudomonas pertucinogena.'" (Office Action, p.5). The Examiner argues that "(w)hile applicant's amendment does clarify that P.pertucinogena is excluded from the claims, the number and type of bacteria associated with a particular genus is not fixed, but rather changes and evolves over time. As the recitation 'all species of the genus Psuedomonas, except for Psuedomonas pertucinogena' does not have a clear and fixed definition, the inclusion of this language in the claim therefore renders it indefinite." (Office Action, p.5 – 6).

Applicants respectfully traverse this rejection. However, while in no way acquiescing to the validity of the Examiner's rejection, and solely in the interest of expediting prosecution, Applicants have amended the claims to positively recite that the species of Psuedomoas is selected from Pseudomonas aeruginosa, Pseudomonas alcaligenes, Pseudomonas chlororaphis, Pseudomonas fluorescens,

Pseudomonas fragi, Pseudomonas huttiensis, Pseudomonas luteola, Pseudomonas mendocina, Pseudomonas mucidolens, Pseudomonas nitroreducens, Pseudomonas pseudoalcaligenes, Pseudomonas putida, Pseudomonas stutzeri, or Pseudomonas veronii or sequences complementary to the target sequence. Thus, Applicants respectfully request that the rejection be withdrawn.

The Examiner argues that "claims 28 – 31 are indefinite because the claims refer to the claimed kits being 'used' in particular methods/ assays. However, as the claims are to products (not methods), it is not clear how the manner in which the kits are used actually limits the products being claimed." (Office Action, p.6).

Applicants have amended the instant claims to recite the use of the products in the methods/assays being claimed. Accordingly, Applicants respectfully request that the rejection be withdrawn.

The Examiner argues that "claim 33 is indefinite over the recitation of the limitation 'a target sequence of 23S rRNA or rDNA of the species of the genus Pseudomonas selected from the group consisting of:...' (and) (t)he claim does not previously refer to a species or multiple species that might constitute 'the species of the genus Pseudomonas,' and it is not clear from this language whether the claim requires one species, all species, or, e.g. multiple species." (Office Action, p.6).

As discussed above, the claims have been amended to positively recite the species of the genus Pseudomonas encompassed by the invention. Accordingly, Applicants respectfully request withdrawal of the rejection.

In view of the above amendments and remarks, Applicants respectfully request withdrawal of the rejections under 35 U.S.C. §112, second paragraph and allowance of the claims.

35 U.S.C. §112, first paragraph-written description

The Examiner has rejected claims 1 – 12 and 25 – 31 under 35 U.S.C. §112, first paragraph, for allegedly failing to comply with the written description requirement. Applicants respectfully traverse the rejection.

Instant claim 1 recites a PNA probe comprising a nucleobase sequence for the detection, identification and/or quantitation of Pseudomonas, wherein said PNA probe comprises a sequence of 10 – 17 nucleobase subunits in length, and wherein said PNA probe is complementary to a target sequence of 23S rRNA or rDNA of Pseudomonas aeruginosa, Pseudomonas alcaligenes, Pseudomonas chlororaphis, Pseudomonas fluorescens, Pseudomonas fragi, Pseudomonas huttiensis, Pseudomonas luteola, Pseudomonas mendocina, Pseudomonas mucidolens, Pseudomonas nitroreducens, Pseudomonas pseudoalcaligenes, Pseudomonas putida, Pseudomonas stutzeri, or Pseudomonas veronii, or sequences complementary to the target sequence.

As described above, Applicants have amended the claims to positively recite the species of Pseudomonas encompassed by the invention.

The Examples in the disclosure support the recitation of these species. Even further, the Examiner points out that "a recitation of the species in the Table in the claim itself would be supported by the descriptive material in the Table." (Office Action, p.7 – 8). Applicants refer to the Table at paragraph [0125] of the published application, below:

Species	ATCC#	Results
Acinetobacter calcoaceticus	14987	Negative
Aeromonas hydrophila	7965	Negative
Brevundimonas diminuta	19146	Negative
Burkholderia cepacia	25416	Negative
Comamonas testosteroni	17409	Negative
Delftia acidovorans	15668	Negative
Pseudomonas aeruginosa	9027	Positive

Pseudomonas aeruginosa	27853	Positive
Pseudomonas alcaligenes	14909	Positive
Pseudomonas chlororaphis	9446	Positive
Pseudomonas fluorescens	17397	Positive
Pseudomonas fluorescens	13525	Positive
Pseudomonas fragi	4973	Positive
Pseudomonas huttiensis	14670	Positive
Pseudomonas luteola	35563	Positive
Pseudomonas mendocina	25411	Positive
Pseudomonas mucidolens	4685	Positive
Pseudomonas nitroreducens	33634	Positive
Pseudomonas pertucinogena	190	Negative
Pseudomonas pseudoalcaligenes	12815	Positive
Pseudomonas putida	12633	Positive
Pseudomonas putida	17484	Positive
Pseudomonas stutzeri	11607	Positive
Pseudomonas veronii	700474	Positive
Ralstonia pickettii	27511	Negative
Sphingomonas paucimobilis	29837	Negative
Stenotrophomonas maltophilia	13637	Negative

As shown in the Table, the instant claims include a recitation of the species as exemplified in the Table.

Accordingly, Applicants respectfully request withdrawal of the written description rejection and allowance of the claims.

35 U.S.C. §112, first paragraph-enablement

The Examiner has rejected claims 1 – 12 and 25 – 31 under 35 USC §112, first paragraph, for lack of enablement. The Examiner alleges that "the specification, while being enabling for a PNA probe consisting of SEQ ID NO: 1, does not reasonably provide enablement for any probe 'complementary to a target sequence

of 23S rRNA or rDNA of all species of the genus Pseudomonas.'" (Office Action, p.8). Applicants respectfully traverse the rejection.

The instant claims were set forth above. Applicants again point out that the claims, as amended, positively recite the species of Pseudomonas encompassed by the invention.

The MPEP states that the determination that "undue experimentation" would have been needed to make and use the claimed invention is not a single, simple factual determination. Rather, it is a conclusion reached by weighing a combination of factual considerations: the breath of the claims, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, the amount of direction or guidance presented, the presence or absence of working examples, and the quantity of experimentation necessary. In re Wands, 858 F.2d at 737, 8 USPQ2d at 1404. Accordingly, the Examiner must consider considered the above factors in his rejection.

Applicants point the Examiner again to the Examples, specifically to paragraphs [0123] – [0124], which specifically describes use of the PNA probe of SEQ ID NO: 1 targeting Pseudomonas:

> Smears were covered with approximately 50 .mu.L of hybridization solution containing 10% (w/v) dextran sulfate (Sigma Chemical Co., St. Louis, Mo.), 10 mM NaCl (J. T. Baker), 30% (v/v) formamide (Sigma), 0.1% (w/v) sodium pyrophosphate (Sigma), 0.2% (w/v) polyvinylpyrrolidone (Sigma), 0.2% (w/v) ficoll (Sigma), 5 mM Na.sub.2EDTA (Sigma), 1% (v/v) Triton X-100 (Aldrich), 50 mM Tris/HCl pH 7.5 and 500 nM fluorescein-labeled **PNA probe (Flu-OO-CCTACCACCTTAAAC)** targeting Pseudomonas (sensu stricto). Coverslips were placed on the smears to ensure even coverage with hybridization solution, and the slides were subsequently placed on a slide warmer with a humidity chamber (Slidemoat, Boeckel, Germany) and incubated for 90 min at 50.degree. C. Following hybridization, the coverslips were removed by submerging the slides into approximately 20 mL/slide

pre-warmed 5 mM Tris, pH 10, 15 mM NaCl (J. T. Baker), 0.1% Triton X-100 (Aldrich) in a water bath at 50.degree. C. and washed for 30 min. Each smear was finally mounted using one drop of Mounting Fluid and covered with a coverslip. Microscopic examination was conducted using a fluorescence microscope equipped with a FITC/Texas Red dual band filter set. Pseudomonas (sensu stricto) was identified as green fluorescent rods.

The results of the experiments described above are listed in Table 1. As discussed above, the instant claims include a recitation of the species exemplified in the Table, and demonstrate that the PNA probe having the sequence set forth in SEQ ID NO: 1 can be used in the invention as claimed.

Moreover, Applicants provide ample direction in the specification for one of skill in the art to make a PNA probe, for example at paragraphs [0057] – [0062]. At paragraphs [0069] – [0072], the specification teaches what would be required for one of skill in the art to determine percent homology of a probe and a Pseudomonas target sequence.

Taken together, the teachings of the specification and knowledge of one of skill in the art enables one of skill in the art to practice the full scope of the claimed invention without having to resort to undue experimentation. Applicants accordingly request that the rejection be reconsidered and withdrawn.

35 U.S.C. §102(b)

Claims 1 – 12 and 25 – 31 have been rejected under 35 U.S.C. § 102(b) as being anticipated by Lexow (WO 00/39333). The Examiner argues that the Lexow reference "discloses all 65,536 possible PNA octamers (and) such molecules meet the requirements of claims 1 and 3." (Office Action, p.12). Applicants respectfully traverse the rejection.

Instant claim 1 recites a PNA probe comprising a nucleobase sequence for the detection, identification and/or quantitation of Pseudomonas, wherein said PNA probe comprises a sequence of 10 – 17 nucleobase subunits in length, and wherein

said PNA probe is complementary to a target sequence of 23S rRNA or rDNA of Pseudomonas aeruginosa, Pseudomonas alcaligenes, Pseudomonas chlororaphis, Pseudomonas fluorescens, Pseudomonas fragi, Pseudomonas huttiensis, Pseudomonas luteola, Pseudomonas mendocina, Pseudomonas mucidolens, Pseudomonas nitroreducens, Pseudomonas pseudoalcaligenes, Pseudomonas putida, Pseudomonas stutzeri, or Pseudomonas veronii, or sequences complementary to the target sequence.

The teachings of the Lexow reference do not anticipate the claimed invention. Specifically, the Lexow reference does not teach or suggest use of **a PNA probe comprising a sequence of 10 – 17 nucleobase subunits for the detection, identification and/or quantitation of Pseudomonas**.

The Examiner argues that "an ordinary artisan could clearly employ the octamers of Lexow et al. in sequencing...to detect and/or identify and/or quantitate psudomonads." (Office Action, p.9 – 10). The Examiner argues that "as Lexow et al. teach the single base extension of any octamer...Lexow et al. inherently disclose all possible 9mers." (Office Action, p.10).

As pointed out by the Examiner, the '333 reference teaches PNA **octamers** and "possible 9mers" by single base extension. The instant claims recite PNA probes comprising a sequence of 10 – 17 nucleobase subunits. The disclosure teaches, for example at paragraphs [0017] and [0060], that a shorter probing nucleobase sequence can be generated by truncation of the identified sequence.

Accordingly, the Lexow reference does not anticipate the invention as claimed. Applicants respectfully request withdrawal of the rejection and allowance of the claims.

35 U.S.C. §103(a)

Claim 33 has been rejected under 35 U.S.C. § 103(a) as being unpatentable over Ludwig et al (Applied Environmental Microbiology 60(9):3236 – 3244) in view of

Hyldig-Nielsen et al (US 6,169,169 B1). Applicants respectfully traverse the rejection.

Claim 33 has been cancelled, thereby rendering the rejection under 103(a) moot. Accordingly, Applicants respectfully request that the rejection be withdrawn.

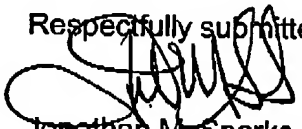
CONCLUSIONS

For the reasons provided, Applicant submits that all claims are allowable as written and respectfully requests early favorable action by the Examiner. If the Examiner believes that a telephone conversation with Applicant's attorney/agent would expedite prosecution of this application, the Examiner is cordially invited to call the undersigned attorney of record.

The Director is hereby authorized to charge any credits or deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to Deposit Account No. 04-1105.

Dated: August 12, 2008

Respectfully submitted,



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